Guideline

EUROPEAN STROKE JOURNAL

European Stroke Journal
2018, Vol. 3(3) 220–226

DOI: 10.1177/2396987318778971
journals.sagepub.com/home/eso
SAGE

European Stroke Organisation certification of stroke units and stroke centres

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Abstract

To improve quality and to overcome the wide discrepancies in stroke care both within- and between European countries, the European Stroke Organisation Executive Committee initiated in 2007 activities to establish certification processes for stroke units and stroke centres. The rapidly expanding evidence base in stroke care provided the mandate for the European Stroke Organisation Stroke Unit-Committee to develop certification procedures for stroke units and stroke centres with the goals of setting standards for stroke treatment in Europe, improving quality and minimising variation. The purpose of this article is to present the certification criteria and the auditing process for stroke units and stroke centres that aim to standardise and harmonise care for stroke patients, and hence become members of the European Stroke Organisation Stroke Unit and Stroke Centre network. Standardised application forms and guidelines for national and international auditors have been developed and updated by members of the European Stroke Organisation Stroke Unit-Committee. Key features are availability of trained personnel, diagnostic equipment, acute treatment and collaboration with other stroke-caregivers. After submission, the application is reviewed by one national and two international auditors. Based on their reports, the Stroke Unit-Committee will make a final decision. Validating on-site visits for a subset of stroke units and stroke centres are planned. We herein describe a novel, European Stroke Organisation-based online certification process of stroke units and stroke centres. This is a major step forward towards high-quality stroke care across Europe. The additional value by connecting high-quality European Stroke Organisation Stroke Unit and Stroke Centre is facilitation of future collaboration and research activities, enabling building and maintenance of a high-quality stroke care network in Europe.

Keywords

European Stroke Organisation Stroke Unit, European Stroke Organisation Stroke Centre, collaboration, high-quality stroke care

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Introduction

After randomised, controlled studies in the 1990s showed better survival and increased rates of independence for people after acute stroke, through care delivered by multi-professional stroke teams on dedicated and geographically marked stroke units (SU),[1] the number of SU increased quickly by the end of the same decade.[2] However, despite this increase, after nearly 20 years, stroke care still varies greatly. At the same time, new principles of acute ischaemic stroke treatment, such as intravenous thrombolytic treatment and endovascular intervention have been introduced and developed.[3] The first hours are also decisive for patients with acute haemorrhagic stroke and growth of haematoma.[4] In addition, the special challenge of stroke care is the long chain of stroke expertise from early management and acute treatment to cause finding, prevention and rehabilitation.

The revolutionary development of acute stroke care started with in vivo cerebral imaging, making rapid differentiation of types of ischaemic and haemorrhagic stroke possible. During the 1980s, treatment after acute ischaemic stroke had only two options, dominated by acetylsalicylic acid and warfarin, done quite equally at stroke treating hospitals. Recombinant tissue plasminogen activator (rtPA), however, raised the profile of acute stroke care. rtPA was first officially approved in 1996 by the Food and Drug Administration in the United States. Germany and several other European countries approved rtPA in 2000, when a Cochrane systematic review confirmed effectiveness, and its use after the official approval increased.[5] However, large differences in rates and types of acute vascular diagnostics and rates of intravenous thrombolysis continued to exist between European countries.[6]

Tele-stroke was established in some countries or regions in Europe in order to provide rapid 'bridging of knowledge' for acute help to select suitable patients for thrombolysis in rural areas.[7,8] Positive endovascular intervention studies from 2015 onwards finally emphasised the necessity of quickly available specialised knowledge and skills for best preservation of the brain. Tele-stroke now contributes in many countries with areas of impaired access to specialised stroke care to gain quick and individualised expert advice with regard to treatment, and, when necessary to arrange rapid transport to the nearest intervention centre.[9] The magnitude of acute intervention effects is very substantial, if patients are diagnosed quickly and cared for by an organised stroke service. Fast application of thrombolytic treatment enhances the chance for good clinical outcome.[10] And for patients with severe stroke, only rapid transport to well-organised and equipped services enhances the chance for best clinical outcome after thrombectomy with number needed to treat of just three, to benefit within due time.[10]

In 2005, the Executive committee of the European Stroke Initiative performed a survey of the status of 886 randomly selected hospitals in 25 European countries, with the main criteria for SU care: including personnel, diagnostic procedures, monitoring, intervention, infrastructure, protocols and procedures.[11] The results showed that less than 9% of hospitals qualified for comprehensive stroke centre (SC) or primary SC, about 40% of hospitals provided a minimum level of stroke care, and about 51% of hospitals provided stroke care below the minimum level.[12] Certifications are a way to improve quality and to equalise stroke care in Europe by connecting high-quality SU and SC for future collaboration and research activities.

In 2007, the European Stroke Organisation (ESO) Executive Committee gave the mandate for developing SU certification, what led to the first ESO SU-Committee recommendations.[13] In face-to-face meetings, these recommendations were transformed to first versions of ESO SU and SC application forms, published in May on the ESO Conference 2016 in Barcelona. Subsequently, online application at this certification platform has been possible (https://www.eso-certification.org/).

This article provides information about the certification process, including application form criteria and information about auditing processes, based on first experiences with ESO-international certification work.

Methods and working processes

ESO SU and ESO SC application forms

The ESO SU and ESO SC are the two defined levels of institutional stroke care. The SU provides stroke care at the basic level, including IV thrombolytic treatment, neuro-intensive care, diagnostics and other key therapy, such as secondary prevention, early treatment of complications and start of rehabilitation. The SC is a fully equipped institution providing the same service as an SU, and in addition offering thrombectomy and other neuro-radiological and surgical interventions. The ESO SU application form is presented in Supplementary Table 1. The ESO SC application form is presented in Supplementary Table 2 (supplementary tables can be found online with this article http://journals.sagepub.com/doi/full/10.1177/2396987318778971).

Each application form has the same seven main criteria for SU care, such as (A) Lead, (B) Personnel, (C) General infrastructure, (D) Investigations, (E) Interventions and monitoring, (F) Teaching, meetings and research, (G) Numbers and quality indicators.

Knowledge, skills and personnel resources at any diagnostic and treatment step are important and are evaluated in the certification process. The seven main criteria in both application forms consist therefore of *must* criteria (that is, essential for certification) and *additional* criteria. In total, they contain 44 criteria for the SU and 49 criteria for the SC. The chain of stroke care starts with acute evaluation for potential thrombolysis and other re-vascularisation intervention, followed by decisions about intensive or semi-intensive stroke care, collection of diagnostic results, and ends at decisions for secondary prevention, rehabilitation and follow-up. For the majority of patients, stroke care continues at the SU after initial neuro-radiologic diagnostics. The SU is defined by specialised collaboration of a multi-professional team at a dedicated, appropriate and geographically clearly defined area with a defined minimal number of beds for patients in need of continuous monitoring.[13] SU combine continuous monitoring, observation and diagnostics. This care continues until the brain is stable. Brain- heart-, lung-, kidney-, liver- and metabolic functions as well as urinary bladder function and swallowing are monitored and treated when necessary, while diagnostic processes are ongoing to find and understand the cause of stroke. Continuous monitoring on SU allows early detection and early treatment of complications in the unstable phase after acute stroke with danger for stroke in progression, cerebral oedema, epileptic seizures and non-cerebral complications. First studies, involving 354 patients showed in 2013 reduced death and disability at discharge or after three months, compared with intermittent monitoring.[14] In addition, first evaluations of physical function, speech- and language functions and cognitive function are performed, and first steps of rehabilitation are started. Adequate nutrition is essential, and social workers and neuropsychologists should be available for patients in need. All these tasks require well-established pathways, preferably documented in local standard operating procedures (SOPs) and attached to the application forms.

In the end, numbers and results of given quality indicators show whether a hospital fulfils the criteria for an ESO SU or for an ESO SC. Frequencies by numbers and hospital statistics have to be officially confirmed by at least two persons of the hospital's administration.

Most decisive criteria are defined as *must* criteria. It is essential for the applicant that the *must* criteria are all completely fulfilled. If there are items missing, more local work has to be done before an application should be sent. However, it may be possible to give a certification as ESO SU instead of ESO SC. Additional criteria are rated and graded from 0 to 3 points. Zero point means that the item is not present at all, 1 means that there is some fulfilment, 2 means still some deficiencies and 3 means complete fulfilment of the requested documentation. The sum of all points will give a rating in adherence with the optimal standard that will be set by members of the SU-Committee. This value may, in the future, also be used for further evaluation of quality at re-certification as well as it may allow comparison of provided stroke care for a hospital, a region or for an entire nation. Certifications are done for European countries with membership of the national stroke organisation in the ESO. In addition, at least one of the leading physicians of the applying SU or SC has to be an active member of the ESO.

Detailed and targeted information has to be provided in English language. But SOPs for investigations and diagnostics and for interventions and monitoring are usually already present at applying hospitals, and these are therefore accepted in the native language for application.

Collaboration with other departments or hospitals has to be confirmed by the clinical lead of the collaborating site. Paediatric and young adult stroke patients have very different diagnostic challenges, compared with stroke at a higher age, and ESO SCs are expected to show their collaboration in the field of paediatric stroke.

There may be hospitals, usually from countries with small populations that have neuroradiology, endovascular intervention, vessel surgery, neurosurgery within their own walls and would in many ways qualify for an ESO SC, but when actual hospital statistics do not have the numbers that are *must* criteria for a centre, these hospitals will be certified as ESO SU. Within their own countries, however, they may be regarded as national SC.

As work with maintenance and update of knowledge and skills in experienced and regularly trained staff is most important for continuous high-quality stroke care, re-certification is mandatory and has arbitrarily been chosen to be done every fifth year. Certified ESO SU and SC will get a reminder from the ESO Head Office, when time for re-certification is approaching. We then expect that some of the primarily certified ESO SU may be re-certified as ESO SC.

The ESO SC and ESO SU certification processes

A flowchart is given in Table 1.

Application. The application has to be written in English. An exception is the main criteria category 'E' in the SC and the SU application forms that permits information about SOPs procedures in the native language.

Table 1. Flowchart of the ESO certification processes for ESO Stroke Units and ESO Stroke Centres.

Responsibility	Working tasks	Time schedule
ESO Head Office	– Administration of the certification processes	– Delegation of working tasks – Communication between auditors and applying hospitals – Schedules site visits – Informs about re-certification 6 months before the time limit
Applying hospital	– Application form after check of *must* criteria	
	– Review	– Additional information should be provided within 3 months
	– Re-certification	– Re-application within 5 years
National auditor	– National audit: thorough check whether all answers are given to the point at any item and in the correct language – Do colleagues that do not work at the applying hospital get a good and correct impression about all services?	– 4 weeks
Members of the ESO SU-Committee	– International audit	– 6 weeks
	– Site visit	– 6 to 8 hours

Any *must* criteria and additional criteria should be answered by the applicant with target information, before supplementary information may be given in order to most clearly portray the SU or SC for colleagues that do not know the applying hospital. Spatial relations of emergency rooms, computed tomography (CT)/magnetic resonance imaging (MRI) and angiography labs by architectural plans with explanations about what to find where have been very contributory. In addition, it is important to present how many clinical staff, including junior doctors and colleagues, are involved in necessary specialities in different functions 24 h a day and 7 days a week. Clear description of how key functions, such as embolectomy or neurosonology, are performed during weekends, periods of sick leave or holidays should be provided. Detailed information should be given about how acute care, types of diagnostics and monitoring, teaching and certification-knowledge, such as updated National Institute of Health Stroke Scales (NIHSS) and modified Rankin Scale (mRS) scoring, rehabilitation and clinical follow-up in an outpatient clinic are organised. Additional information, such as links or copies of internal telephone lists of colleagues in other departments help to show the size and functions of the applying hospital. Finally, hospital statistics, confirmed by the names, positions and signatures of at least two members of the hospital's administration, show the key quality results for the door to CT, CT to needle and CT to intervention time.

National auditor. National auditing performed by an ESO commissioned auditor is the first step towards certification after the application has been sent to the ESO Head Office. Collaboration between the applying hospital and the national auditor, who is a member of the ESO is required, and is regarded as a stimulation process in order to create better understanding and working for increased quality in national stroke care. National auditors cannot audit their own hospital. One of the key functions is to understand and help the applicant to present their hospital by important core information. National auditors should be members of the ESO with good clinical knowledge to all the different links in the chain of stroke care. They should be active in clinical work and they should have experience in research. They have to check carefully all *must* criteria and additional criteria if any information in the application form is missing, and if all information is specified to the actual question in the appropriate language. National auditors will be critical if supporting data files are not systematically organised or referenced. The second national auditing key function is to assure that the SOPs in the national language meet and fulfil the necessary information asked for. Missing information will be marked in the report to the ESO Head Office by the national auditor, and the application will be returned to the applying hospital with the requirement to give necessary additional information within three months. Only approval of the application form by the national auditor enables auditing by the members of the SU-Committee. There may be national differences, for example concerning outpatient clinics, and in such cases, the national auditor should give explanatory information in the report to the ESO Head Office.

ESO auditor. The provision of targeted information for all criteria in the approval form is essential for a good international auditing process. The SU-Committee has 10 members at a maximum. All members are neurologists or stroke physicians from 10 European countries, well experienced in clinical work, teaching and research. Many of them have done high-quality work for improvement of stroke care for years, and several of them have contributed to national certification work. It is intended in future to recruit SU-Committee members from national auditors, and to keep former SU-Committee members in the group of national auditors, when membership term in the ESO SU-Committee reaches its end. At the moment, auditors are nominated by the SU-Committee among Fellows of the ESO and by invitation from national stroke societies. Members of the SU-Committee are performing international audits during their tenure for four years. The chair of the SU-Committee has a working period of eight years at the most. Active ESO SU-Committee members are not permitted to undertake audits for hospitals from their own country, or in any case of conflict of interest with the applying department lead. Former SU-Committee members continue working as national auditors without an official time limitation, and as long as each is involved in clinical, teaching and research work. We aim to maintain a balance between West- and East and North- and South European countries with regard to the SU-Committee composition.

Two auditors, one of whom is responsible for leading the audit, form a team and submit their evaluation to the ESO Head Office within six weeks. If auditors do not agree in their final decision, a third member of the SU-Committee will subsequently be involved. In case of failure to comply with the requirements, an adapted resubmission from the applying hospital is required within three months. The auditing process should in any case be considered as tool to enhance quality standards of care, and all auditors are requested to neutrally support this attitude. The board of all SU-Committee members makes final approval on the certification as ESO SU or ESO SC, independently from the national auditor. The national auditor is informed about the final decision about certification approval or rejection, together with the applying hospital.

Site visits. Validating site visits will be performed on selected sites after decision by members of the SU-Committee, especially if critical issues cannot be resolved through correspondence. Other site visits will be performed on a random basis.

At least two-month notice will be given before a planned site visit. The visit to the site will usually be complete within 6 to 8 hours. The auditing language is English, but possible translation processes in order to speak with members of different professional care giving groups may lead to expansion in time. The site visit by the national auditor and members of the SU-Committee starts by 'walking the patient's journey' from doors of admission to first CT- and MRI scanning, site of thrombolysis and embolectomy, tele-stroke communication and logging, location and geographical relations of emergency rooms, the intensive care unit and continuous monitored and non-monitored beds on the SU. Members of the SU-Committee will talk with involved personnel at different diagnostic stations about working plans, collaboration, teaching, and eventually research work and contribution to research. The rest of the time is spent on personnel lists, reviews of recently discharged patients and documentation of diagnostics, medication and started rehabilitation processes, review of teaching programs and hospital statistics. In summary, site visits will cover the entire chain of acute stroke care.

Discussion

We describe the new ESO certification processes for ESO SU and ESO SC, that necessitates criteria being met in the domains of clinical leadership, personnel, infrastructure, investigations, interventions, monitoring, teaching, meetings, research and quality indicators. In total, 44 criteria for the SU and 49 criteria for the SC have to be addressed by applicants.

Experiences with first applications were answered questionnaires entirely in the native language, although the main part has to be answered in English. In some cases short, non-informative responses were given, and in one other case a very large data file was uploaded, and auditors were required to pick the correct answer from that file. However, targeted and concise information should be provided for all of the 44 or 49 items in order to give the auditors a good overview within a reasonable timeframe. Several applicants ignored the required *must* criteria, despite our emphasis that they function as absolutely 'knock-out' criteria. When *must* criteria are not fulfilled, it will not be possible to obtain a certificate as ESO SC or SU.

Many hospitals now focus on acute intervention during the first hours after stroke onset. Future medication may improve and new mechanical clot retrievers or other clot removal treatments may appear, but the principles of fast clot removal have been developed and documented by first positive interventional trials in 2015.[15] However, the ESO application forms show the challenge and the chain of stroke care also after intervention. Continuous monitoring by a trained stroke team that has focus on continuous maintenance of knowledge, skills and quality is necessary for

observation until brain functions are stable. Rehabilitation starts simultaneously and continues for patients in need. The effects of tele-stroke that support the delivery of quality stroke care in Europe are documented,[16] and some countries have made early investments to build this up in order to improve safety and quality in acute stroke treatment for rural hospitals.[17–19]

High-quality stroke care means good collaboration within the stroke team, other departments, stroke-interested cardiologists and other colleagues in clinical and rehabilitation medicine for treatment and follow-up of physical-(including also vision and hearing), cognitive-, language-, speech- and swallowing functions.

At the moment, for many minor hospitals it is still a big challenge to implement and follow established guidelines for acute stroke care. It may sound easy, but probably the most important task is to transform our knowledge into practical, adequate and up-to-date stroke care.

Many departments with specialists of brain diseases in Europe still do not have continuous monitoring during the unstable period after acute stroke, whereas such monitoring has been established already many decades ago for patients in need for post-traumatic and post-operative care and for patients with unstable or post-intervention coronary heart disease. We hope that ESO certification '*musts*' contribute to show this necessity in stroke care for best functional outcome.

ESO SU and ESO SC certifications are not a substitute for well-established national certification work, although there may be a profit from information exchange. But ESO certifications will be of additional value for unified stroke care, connecting major and qualified SU and SC for future collaboration and research. We expect more nations to develop their own certification processes in future. However, as European history in stroke care has shown, there are large differences within countries, and the ESO SU-Committee intends especially to help hospitals from nations without developed national certifications to apply for approval as site with updated international stroke care. Certified as ESO SC or ESO SU, they will function as national SC, standing for national excellence, helping their nation to further development of high-quality stroke care. This will facilitate future collaboration and research activities for building and maintenance of a high-quality stroke care network in Europe.

The authors are aware of other types of certification. In the United States of America, there are several associations, such as the Brain Attack Coalition, The Joint Commission, the American Heart Association and the National Stroke Association, that have formed since 2000, and contributed to increased quality of stroke care. Since 2003, primary SC certification, and since 2012, comprehensive SC certification has been possible.[20] These are comparable to the ESO SU and SC certifications. However, as the ESO's certification system is based on non-paid, voluntary work of stroke specialists, it is not possible to regularly perform regularly site visits for annual re-certification, as undertaken by The Joint Commission.[20] The ESO SU-Committee agreed on re-certification every five years, plus random site visits.

Some European nations have developed their own certification programs, approximating that of the ESO's. Future collaboration with national and regional stroke organisations is therefore intended to stimulate national auditing by site visits, with certification and re-certification that may then also lead to certification by the ESO. It is anticipated that this would form the foundation for an international collaboration in clinical practice and research. The Joint Commission offers also certification for minor 'Acute Stroke Ready Hospitals', with access to telemedical equipment and for 'Thrombectomy-Capable Stroke Centers' with a focus on intervention (https://www.jointcommission.org/certification/advanced_certification_comprehensive_stroke_centers.aspx). The ESO SU and SC certifications are developed to focus deliberately on the whole chain of stroke for research network building. Finding the cause and assessing prognosis after acute stroke are especially important for our young patients with biggest challenges to fulfil todays' dominating working conditions with less manual and more multi-tasking work. This demands comprehensive recovery and rehabilitation in vocation, lifestyle and social domains.

Pre-hospital stroke management is set to attract increasing attention in future, as improved quality of neuro-imaging and compact and portable imaging machines may lead to highly equipped transport systems that would shorten time to thrombolysis. This may lead to a future focus on stroke-to-thrombolysis and stroke-to-groin puncture times, instead of in-hospital measurements. However, to date, the ESO SC and SU certification processes consist of SC and SU hospital-based activities only. Pre-hospital stroke management plays an important but indirect role via establishing the best and most rapid patient transfer routines to either a SU or a SC, underpinned by educated and engaged general practitioners and ambulance personnel plus acute medical communication networks with the help of health authorities. The role of stroke physicians from SU and SC will be to give advisory support and enhance coordination of activities.

Acknowledgements

We want to thank the following former members of the ESO Stroke Unit-Committee for valuable contributions to develop the ESO SC and SU application forms: Juan Arenillas

(Spain), Hanne Christensen (Denmark), Markku Kaste (Finland), Thierry Moulin (France) and Helen Rodgers (United Kingdom). We are also very grateful for the management and technical support from the ESO Head Office, Basel, Switzerland, and especially we want to thank Annina Giger.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical approval

Ethical approval was not necessary for the results of this manuscript.

Informed consent

Informed consent was not actual or necessary for this manuscript.

Guarantor

A special guarantor does not exist. The former and actual members of the Stroke Unit-Committee have developed the work.

Contributorship

All contributors have either co-authored the manuscript or are mentioned in.

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